REMARKS

Both the Abstract and the Title are objected to. The objections are traversed. However, amendments to the specification are deemed to moot these objections.

The new claims use language which limits the claimed tablet to one having only two components (a core and a single film coating), the core of which has only one pharmaceutically active substance. Claim 23 recites a reduced range of MCC supported by page 2, paragraph 8. Claim 24 is supported by Example 1. No new matter has been added.

Claims 15 and 16 are rejected under 35 USC 112 as indefinite. The rejection is traversed. However, in new claims 17 and 21 it is made clear that the amounts are based on the weight of the coating alone, which the Examiner has noted are implied. The rejection is deemed to be moot.

Claims 9-11, 13, and 14 are rejected under 35 USC 103 as obvious solely over Bartholomaeus, USP 6,558,701 ("US'701"). The rejection is traversed. The teaching of US'701 is totally irrelevant to the present invention. US'701 teaches a multilayer (minimum of three) tablet with two active ingredients and an internal separation layer. This layer is quite different from a coating. Coatings are mentioned only in passing in US'701 as optional embodiments. The Examiner has dismissed the distinction between a coating and a separation layer on the basis that their compositions and not their labels must be evaluated. Applicants disagree that compositions alone are relevant. The "labels" coating and separation layer are not merely names in either the reference or the application. Rather, they define the positions and functions of these moieties. In the present application, since there is only one core moiety, a "separation layer" would be a meaningless term and is not used. In the case of US'701, the reference recites both a separation layer and a coating and itself distinguishes between the two as to both composition and function. In US'701 the separation layers are positioned between the layers of actives in the core and function to separate the active-compound-containing layers from each other without, however, impairing their release profiles upon oral administration (col., 1, ll. 50-64). Controlled release of the actives may also be achieved by a suitable "retard coating" which can be made from water-insoluble waxes or polymers. The "retard layer" may additionally itself

comprise "non-retarded" (*sic*) polymers to modify the release rate of the actives and may also be coated by additional coatings (col. 4, ll. 4-32). The retard layer never comprises non-retarded polymers alone. There is no teaching or suggestion in US'701 to coat the core of a tablet containing a single active with a single coating comprising 60-70% (w/w) hydroxypropyl methylcellulose, 8-12% (w/w) stearic acid, 5-15% (w/w) microcrystalline cellulose, and 10-20% (w/w) titanium dioxide, as in the present claims. Since the reference itself distinguishes between the separation layer and the coatings, the Examiner cannot equate the two. The composition of one has no relevance to the composition of the other. Nothing that the reference teaches about the composition of the separation layer can be transferred to the coatings. Furthermore, even if the teaching regarding the separation layer could be applied to the coating, the amounts of disclosed components such as MCC and HPMC are completely outside the scope of the corresponding compounds of the present invention. The Examiner herself recognizes the limited relevance of US'701 by stating that the reference does not teach diclofenac in the core, that it does not teach that the diclofenac-containing layer is coated, and that the reference does not teach stearic acid. Notwithstanding these significant differences between US'701 and the present invention, the Examiner nevertheless concludes that it would be obvious "to prepare a tablet with more than 3 layers or with diclofenac in the core" to arrive at a coated diclofenac tablet (in the prior Action, which has been incorporated into the present Action by the Examiner). This conclusion is totally without basis in the reference.

The Examiner had continued the rejection by arguing that "optimization of parameters" would lead to the desired result. This basis of rejection is also traversed. It had been requested that the Examiner specifically identify where in US'701 it is suggested to delete one of the two active ingredients, where in the reference it is suggested that the composition of the separation layer be applied to the optional coatings, where in the reference it is suggested that the coatings are not to be optional, where in the reference it is suggested that by radically altering the composition of the separation layer a coating can be achieved that exhibits the unexpected benefits of the present invention, and that she otherwise specifically recite what guidance US'701 provides to the practitioner to lead to the "desired result". Such support for the rejection has not been provided, only the repetition that hardness and compressibility are desired results, neither of which are claimed to be properties of the present invention. Unguided experimentation by one of ordinary skill in the art to improve hardness and compressibility would not lead to or make obvious the claimed tablet. A *prima facie* case of obviousness requires more. Furthermore, the exhibition of surprising and unexpected properties can rebut an obviousness rejection. The specification

provides evidence of such unexpected properties. The Examiner's attention is directed to the Comparative Example, which demonstrates the multiple advantages (process time, process complexity, and taste) of a single-coat tablet according to the invention, when compared to a two-coat tablet.

Claims 9-14 are rejected under 35 USC 103 as obvious over US'701 in view of Humbert-Droz, USP 6,083,531 ("US'531"). The rejection is traversed. However, the limitations of claims 15 and 16 (which are free of this art) have been incorporated into the new claims. Therefore, the rejection is deemed to be moot.

Claims 9-11 and 13-16 are rejected under 35 USC 103 as obvious over US'701 in view of De Haan, US 2006/0051420 ("US'420") and SEPTIFILM LP Product page (SEPTIFILM"). The rejection is traversed. The Examiner states that US'701 teaches a multi-layered dosage form with a diclofenac layer "surrounded by a layer...". This is a mis-characterization of the teaching of this reference, as discussed above. The diclofenac layer in the reference must have a separation layer in intimate contact therewith, not a surrounding layer comprising MCC, HPMC, etc.. The separation layer does not surround the diclofenac layer. US'420 teaches a dosage form wherein the degradation of an active compound is delayed by use of a "wrap" coating, which may be a film, but is preferably a sugar or sugar film coating (abstract). Within the non-preferred genus "film" are listed a large number of film materials. It is taught that not all of the film materials have the desired stabilizing effect (**[0013]**). Thus, the Examiner's argument is that it would be obvious to one of ordinary skill in the art to select, without undue experimentation, a film to be chosen from a genus of less desirable films, after being made aware that some of these less desirable films are ineffective for stabilizing the active ingredient in US'420. It is deemed by applicants that one of ordinary skill in the art, having been advised that films are less desirable and that certain films are ineffective with regard to the active ingredient in US'420, would prefer to not use any of the less desirable films. It is rather more likely that said person would select a sugar or sugar film coating, all of which function well with the active compound of the reference and, thus, would appear to be more likely to succeed if applied to another active; i.e., the reference teaches away from the coating of the present invention. Furthermore, the combination of US'420 and US'701 would result in a multi-layer coated tablet, wherein the layers of actives are themselves separated by separation layers. SEPTIFILM adds nothing to the Examiner's argument, since it only teaches that certain films were known in the art; i.e., that which is known from the specification (see Example 1).

Claims 9, 13, and 14 are rejected under 35 USC 103 as obvious over Ting, WO 99/51209 ("WO'209"). The rejection is traversed. The teaching of WO'209 has no relevance to the present invention. WO'209 teaches a two- (optionally three-) compartment dosage form consisting of 1) an innermost (when present) compartment containing no active ingredient but only polymers, 2) a next compartment containing active and polymers for immediate release of an active, and 3) a surrounding outermost, "extended release" compartment containing active and a combination of hydrophobic and hydrophilic polymers designed to retard release of the active in said and the next inner compartments, but to retain the shape of the drug delivery system for some extended period of time. Ignoring the inert innermost core, the other two compartments each contain a combination of active drug and polymers.

Again the Examiner continues the rejection by arguing that "optimization of parameters" would lead to the desired result. This basis of rejection is also traversed. If the Examiner persist in the argument, it is requested that she specifically recite what guidance WO'209 provides to the practitioner to lead to the "desired result", especially in view of the fact that an extended release outer compartment is not one of the objectives of the present invention. It is noted that the Examiner only recites hardness and compressibility as a desired result, neither of which are presently claimed to be properties of the present invention. Furthermore, the limitations of claims 15 and 16 (which are free of this art) have been incorporated into the new claims. Therefore, the rejection is deemed to be moot.

Claims 9-14 are also rejected under 35 USC 103 as obvious over WO'209 in view of US'531. The rejection is traversed. The comments provided above with regard to these references are repeated. There is no basis for combining these references since no combination of the uncoated four-component, rapidly dissolving tablet of US'531 and the dosage form of WO'209 which comprises an extended release outermost compartment could possibly lead one to the coated tablet of the present invention. Merely because they are both concerned with the tableting art and disclose similar or overlapping components is not the basis for a rejection under the statute. Furthermore, the limitations of claims 15 and 16 (which are free of this art) have been incorporated into the new claims. Therefore, the rejection is deemed to be moot.

All the claims are rejected under 35 USC 103 as obvious over WO'209 in combination with Humbert-Droz (US'531.) as applied to claims 9-14 and further in view of Kurihara, US 4,341,563 ("US'563") and SEPTIFILM. The rejection is traversed. The

comments provided above with regard to the primary references and SEPTIFILM are repeated. US'563 is cited for its description of a protective coating containing TiO_2.

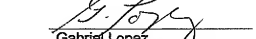
No combination of the dosage form of WO'209 (which comprises actives in two compartments: an extended-release outermost compartment substantially enveloping an inner immediate-release compartment) and the uncoated four-component, rapidly dissolving tablet of US'531 could possibly lead one to the coated tablet of the present invention. The Examiner recognizes (page 13) that obviousness can only be established by combining or modifying the prior art where the prior art provides some teaching, suggestion, or motivation to do so. In the present case, US'531 is used to supplement the teaching of WO'209 with regard to a salt form of diclofenac and the dosage thereof (also at page 13). But this misses the point that the combination of the two references would not lead to the tablet of the present invention, whether or not one of ordinary skill in the art would be motivated to combine them. The Examiner concludes that from these two references it would be obvious to prepare a tablet as presently claimed. Applicants traverse this conclusion, since the combination would produce a two-chambered tablet comprising delayed- and immediate-release compartments each containing an active. This is not the claimed invention.

The disclosure of various ingredients by US'563 does nothing to cure this basic deficiency in combining the first two references since the teaching of any additional ingredients could not possibly lead one to proceed from the first two references to the present invention.

It is requested that the amendments be entered and that the Examiner reconsider the objections and rejections in view of the amendments and remarks and that the case be passed to issue.

Should the Examiner believe that a telephonic interview with applicant's undersigned attorney would advance the status of this prosecution, she is respectfully invited to contact the undersigned at the below-indicated telephone number.

Respectfully submitted,



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